The Thirty-seventh World Health Assembly,

Considering Articles 2(u), 21(d) and (e) and 23 of the Constitution;

Considering resolutions WHA3.8, WHA18.7 and WHA26.32 adopted by the Third World Health Assembly, the Eighteenth World Health Assembly and the Twenty-sixth World Health Assembly respectively, recommending the adoption of certain international standards and units for biological substances;

RECOMMENDS

(1) that Member States of the organization recognize officially the international standards and international reference preparations and units for biological substances enumerated in the two lists annexed to this resolution, which supersede the lists recommended in resolutions WHA3.8, WHA18.7 and WHA26.32;

(2) that these standards and units or their equivalents be cited in the relevant national pharmacopoeias;

(3) that, where applicable, these standards and units or their equivalents be recognized in relevant national regulations;

(4) that in those countries which do not possess a national pharmacopoeia or national standards, when it is necessary that the potency of the product should be stated on the label, such potency be expressed in international units;

Considering also the need to make these international biological standards available to Member States in the most expeditious and convenient manner, as a contribution towards enabling an acceptable level of quality of biological substances used in medicine to be achieved;

Recognizing the value and utility to Member States of these international units, as well as of international units defined for a number of international reference preparations of biological substances, in the national control of biological products;

1. AUTHORIZES the Director-General, where necessary for the use of regulatory agencies of Member States, to make additions to or replacements of these international biological preparations, subject in each case to the satisfactory completion of the technical procedures now established of international collaborative studies and assays and under the advice of the members of the Expert Advisory Panel on Biological Standardization or other experts designated to deal with the standardization of particular biological substances;

2. REQUESTS the Director-General to inform Member States periodically when such international biological preparations are established and their international units have been defined;

3. INVITES the Director-General to inquire periodically of Members regarding the use being made of these international standards and other biological preparations in their countries in the control of biological products.

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Committee B, third report)